

IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

1. (Currently amended) A method of improving sexual performance in a subject in need thereof, comprising the steps of:
 - (a) administering a pharmaceutical composition to the skin of the subject, the composition comprising:
 - i. ~~a pharmacologically effective amount of~~ about 1% to about 2% testosterone,
 - ii. ~~a penetration enhancer~~ about 0.1% to about 5% isopropyl myristate,
 - iii. about 30% to about 98% a-C1-C4 alcohol, ~~and~~
 - iv. about 0.1% to about 5% a-gelling agent ~~forming a hydroalcoholic gel formulation~~, and
 - v. water in an amount sufficient to total 100%,wherein the percentages of the components are weight of the composition; and
 - (b) administering a pharmacologically effective amount of a phosphodiesterase inhibitor to the subject after the administration of the gel formulation.
2. (Cancelled)
3. (Cancelled)
4. (Original) The method of claim 1, wherein the alcohol comprises at least one of ethanol, 2-propanol, n-propanol, or mixtures thereof.
5. (Canceled)
6. (Currently amended) The method of claim 1, wherein the ~~hydroalcoholic gel~~ composition ~~formulation~~ is administered in a single dose or divided dose.

7. (Canceled)
8. (Previously presented) The method of claim 1, wherein the inhibitor is selected from the group consisting of a type III phosphodiesterase inhibitor, a type IV phosphodiesterase inhibitor, and a type V phosphodiesterase inhibitor.
9. (Currently amended) The method of claim 1, wherein the inhibitor is a type V phosphodiesterase inhibitor selected from the group consisting of sildenafil, sildenafil citrate, zaprinast, ~~MY5445~~ 1-(3-chlorophenylamino)-4-phenylphthalazine, and dipyridamole, or an enantiomer, isomer, or salt thereof.
10. (Original) The method of claim 1, wherein the inhibitor is sildenafil citrate administered in an amount of about 25 mg to about 200 mg.
11. (Original) The method of claim 1, wherein the inhibitor is sildenafil citrate administered in an amount of about 25 mg, 50mg, or 100mg.
12. (Currently amended) The method of claim 1, wherein the inhibitor is administered via a route selected from the group consisting of orally oral and intranasal.
13. (Original) The method of claim 10, wherein the sildenafil citrate is administered orally in an amount of about 25 mg, 50 mg, or 100 mg.
14. (Original) The method of claim 12, wherein the sildenafil citrate is administered intranasally in an amount of about 10 mg, 20 mg, or 40 mg.
15. (Original) The method of claim 1, wherein the subject achieves hormonal steady state levels of testosterone.
16. (Original) The method of claim 1, wherein the subject is hypogonadal.
17. (Cancelled)
18. (Cancelled)

19. (Currently amended) The method of claim ~~[[18]]~~1, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.
20. (Currently amended) The method of claim 1, wherein the gelling agent is selected from the group consisting of polyacrylic acid~~[[,]]~~ and carboxymethylcellulose.
21. (Currently amended) The method of claim ~~[[1]]~~20, wherein the gelling agent is polyacrylic acid ~~present in a concentration range from about 0.1 to about 5% weight to weight of the composition.~~
22. (Original) The method of claim 1, wherein the alcohol is present in a concentration of about 72.5% weight to weight of the composition.
23. (Currently amended) The method of claim 1, wherein the testosterone is present in an amount of ~~concentration range from about 1.0% to about 10.0%~~ weight to weight of the composition.
24. (Canceled)
25. (Currently amended) The method of claim 1, wherein the pharmaceutical composition comprises:
- (a) about 1% ~~0.1% to about 10%~~ testosterone;
 - (b) about 72.5% ~~30% to about 98%~~ alcohol selected from the group consisting of ethanol and isopropanol;
 - (c) about 0.5% ~~0.1% to about 5%~~ isopropyl myristate;
 - (d) about 1% ~~0.1% to about 5%~~ of a gelling agent; and
 - (e) water in an amount sufficient to total 100%
- wherein the percentages of the components are weight of the composition.
26. (Original) The method of claim 1, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet and a multiple dose packet.
27. (Currently amended) A method of improving sexual performance in a subject in need thereof, comprising the steps of:

(a) administering a pharmaceutical composition to skin of the subject, the composition comprising: [I, II]

i. ~~a pharmacologically effective amount of about 1% to about 2%~~
testosterone,

ii. ~~a penetration enhancer~~ about 0.1% to about 5% isopropyl myristate,

iii. ~~about 30% to about 98% a C1-C4 alcohol, and~~

iv. ~~about 0.1% to about 5% a gelling agent forming a hydroalcoholic gel formulation,~~

v. water in an amount sufficient to total 100%

wherein the percentages of the components are weight of the composition; and

(b) administering a pharmacologically effective amount of a pharmaceutical agent for treating erectile dysfunction to the subject after the administration of the gel formulation.

28. (Cancelled)

29. (Cancelled)

30. (Original) The method of claim 27, wherein the alcohol comprises at least one of ethanol, 2-propanol, or n-propanol, and mixtures thereof.

31. (Canceled)

32. (Currently amended) The method of claim 27, wherein the composition ~~hydroalcoholic gel formulation~~ is administered in a single dose or divided dose.

33. (Canceled)

34. (Original) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is selected from the group consisting of pentoxifylline, yohimbine, apomorphine, alprostadil, papaverine, and phentolamine, or a combination, salt, derivative or enantiomer thereof.

35. (Original) The method of claim 34, wherein the pharmaceutical agent for treating erectile dysfunction is apomorphine administered orally in an amount of about 2 mg to about 3 mg.
36. (Previously presented) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is administered orally.
37. (Original) The method of claim 27, wherein the subject achieves hormonal steady state levels of testosterone.
38. (Original) The method of claim 27, wherein the subject is hypogonadal.
39. (Cancelled)
40. (Cancelled)
41. (Currently amended) The method of claim ~~[[40]]~~27, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.
42. (Currently amended) The method of claim 27, wherein the gelling agent is selected from the group consisting of polyacrylic acid~~[[,]]~~ and carboxymethylcellulose.
43. (Currently amended) The method of claim ~~[[27]]~~42, wherein the gelling agent is polyacrylic acid ~~present in a concentration range from about 0.1% to about 5% weight to weight of the composition.~~
44. (Original) The method of claim 27, wherein the alcohol is present in a concentration of about 72.5% weight to weight of the composition.
45. (Currently amended) The method of claim 27, wherein the testosterone is present in an amount of concentration range from about 1% 0.1% to about 10.0% weight to weight of the composition.
46. (Canceled)
47. (Currently amended) The method of claim 27, wherein the pharmaceutical composition comprises:
- (a) about 1% ~~0.1% to about 10%~~ testosterone;

- (b) about ~~72.5%~~ ~~30% to about 98%~~ alcohol selected from the group consisting of ethanol and isopropanol;
- (c) about ~~0.5%~~ ~~0.1% to about 5%~~ isopropyl myristate;
- (d) about ~~1%~~ ~~0.1% to about 5%~~ of a gelling agent; and
- (e) water in an amount sufficient to total 100%

wherein the percentages of components are weight to weight of the composition.

48. (Original) The method of claim 27, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet, and a multiple dose packet.

49. (Cancelled)

50. (Cancelled)

51. (Cancelled)